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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/888,959 | 06/25/2001 | Richard Ian Christopherson | DAV1139.001C1 | 2583 |
| 500 | 7590 | 02/04/2005 | EXAMINER | |
| SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092 | | | HOLLERAN, ANNE I. | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,959

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed October 4, 2004 is acknowledged.

Claims 1, 2 and 7-21 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The declaration of Richard Ian Christopherson filed under 37 C.F.R. 1.132 on October 4, 2004, has been considered.

Claim Rejections Withdrawn:

4. The rejection of claims 1, 2 and 7-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to claim 1.

5. The rejection of claims 1, 2, 7, 8, 11, 15 and 18-21 under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Valet (cited in a previous Office action) is withdrawn upon further consideration.

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6. The rejection of claims 1, 2, 7, and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Orfao de Matos Correia E Vale (U.S. Patent 5,538,855; issued 07/23/1996; cited in the IDS) is withdrawn upon further consideration.

Claim Rejections Maintained:

The following rejections are considered together, because the arguments presented are the same for both rejections.

7. The rejection of claims 1, 2, and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Terstappen (U.S. Patent 5,234,816; cited in a previous Office action) is maintained for the reasons of record. The rejection is withdrawn for claims 7-17.

8. The rejection of claims 1, 2, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 4,591,570; issued May 27, 1986; cited in a previous office action) in view of Verwer (U.S. Patent 5,605,805; issued 02/25/1997). The rejection is withdrawn for claims 7, 9-15 and 17.

Applicants' arguments have been carefully considered, but fail to persuade. The declaration of Richard Ian Christopherson has also been considered.

Applicants argue that the rejection should be withdrawn because Chang fails to teach a step of establishing a discriminatory image of antigen expression, which image expresses a characteristic of a type of leukemia. Applicants further assert that this deficiency is not remedied by any of the secondary references, Terstappen, Skfjdkal, cretklj.

This argument is not found persuasive because the active step that is recited in claim 1 is “determining which surface marker antigens have bound to which immobilized immunoglobulin molecules”, which is a step that is taught by Chang. The language concerning “establishment of a discriminatory image” is part of a “thereby” clause, and therefore, appears to be a statement of an inherent result produced by performing the step of “determining which surface marker antigens have bound to which immobilized immunoglobulin molecules”.

Applicants further argue that because Terstappen’s flow cytometry method requires a sequential analysis of antibody binding that combining the teachings of Terstappen with those of Chang would change the principle of operation of Chang. This argument is unpersuasive because Terstappen is relied upon to demonstrate that it is well known in the art to use various surface marker antigens, such as CD antigens, for the purpose of discriminating one type of leukemia from another. Terstappen demonstrates how to differentiate between a B-lymphoid, a T-lymphoid, and a myeloid lineage type of leukemia by examining the binding patterns of white blood cells in a patient sample to antibodies specific for CD10, CD19, CD20, CD5, CD3, CD22, CD7, CD33, CD13 and HLA-DR (see Table II, Columns 7 and 8).

Applicants also argue that because Terstappen is concerned with the use of flow cytometry and with how flow cytometry data is analyzed for the purpose of classifying leukemias, there is no suggestion to alter the method of Terstappen by using the methods of

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Chang. This argument mischaracterizes the rejection. The rejection of the claims is based on the teaching of Chang that antibodies that bind to cell surface markers may be bound to a solid support for the purpose of determining whether certain cells will bind to these antibodies. Binding of cells to the antibodies bound to the solid support is a demonstration that the cells express antigens to which the bound antibodies bind. The teaching that is missing from Chang is that the method may be used for the purpose of determining the nature of the antigens expressed in a sample of cells from a leukemia patient. However, work has been done in the field of immunophenotyping, as evidenced by Terstappen, and it would have been *prima facie* obvious at the time the invention was made to have altered the method of Chang to include the use of antibodies that bind to CD antigens for the purpose of classifying leukemias. It would have been *prima facie* obvious because Terstappen teaches the relevant CD antigens for the purpose of discriminating between different types of leukemias.

Applicants have also presented a declaration by Ian Richard Christopherson as part of the rebuttal of the rejections under 35 U.S.C. 103. In the declaration it is stated that the methods of Chang could not be reproduced, therefore, making the suggestion that Chang is not enabling. One assertion that is made is that antibodies adhered directly to glass do not reliably remain adhered to the surface of the glass unless the surface is first derivatized, and that this derivatization technology was not available at the time Chang made his invention. Then, the declaration offers data to support this assertion, where an experiment was performed comparing the use of nitrocellulose film, silanated glass slides and plain, acid-washed glass slides in an antibody binding assay. However, this experiment appears to demonstrate that in the case of silanated glass slides or acid-washed glass slides there is too much non-specific binding, and

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does not provide evidence that the adherence of antibodies to glass slides was unreliable.

Furthermore, the experiment summarized in the declaration does not replicate the working example of Chang, because Chang used calf serum as a blocking agent to block uncoated space and binding sites (col. 5, lines 58-63), whereas the experiment described in the declaration uses 5% milk. This might be an important difference because Current Protocols in Molecular Biology (Wiley InterScience, 2004, John Wiley & Sons), the use of 5% milk may interfere nonspecifically with binding.

9. The rejections of claims 1, 2, 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeffler (U.S.P.G. Pub 2002/0164656; published 11/07/2002; effective filing date 02/04/1998) in view of Terstappen (U.S. Patent 5,234,816; cited in a previous Office action). The rejection for claims 7-17 is withdrawn.

Applicants arguments have been carefully considered but fail to persuade. Applicant asserts that Hoeffler in view of Terstappen fails to make obvious the claimed invention because Hoeffler describes a method for screening very large numbers of uncharacterized antibodies, and that the antibodies are unknown rather than the applied antigens. This argument is not found persuasive because Hoeffler clearly contemplates using known antibodies in claim 28, which is drawn to a method of diagnosing a disorder comprising contacting an array of antibodies specific for one or more antigens characteristic of a disorder. Also, at paragraphs 74-76, Hoeffler teaches methods using previously characterized antibodies. Applicant further argues that Hoeffler fails to suggest the claimed inventions because Hoeffler uses a cell lysate instead of whole cells. This is not found persuasive because the claims are drawn to methods of obtaining a "biological

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specimen”, and fails to characterize the biological specimen. Therefore, the current claims read on methods using cell lysates.

New Grounds of Rejection:

10. Claims 1, 2, and 7-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that applicant has failed to describe the genus of seven surface markers selected from the group that would be useful for identifying a type of leukemia in a human subject.

Claim 1 has been amended to comprise the step of contacting a sample with an array of immunoglobulin molecules immobilized to a solid support, where the immunoglobulin molecules are specific for surface marker antigens, and wherein at least seven of the surface marker antigens are selected from the list consisting of a list of 43 CD antigens and also glycoporphin A, HLA-DR, KOR-SA3544, and FMC7. While the specification contemplates arrays that minimally contain 7 antibodies, the specification contains no examples of sets of 7 antibodies that would be useful for performing the claimed methods, and specifically would result in the establishment of a discriminatory image of antigen expression and which expression is characteristic of a type of leukemia. The results provided in the specification apply to arrays containing a much larger number of antibodies. Therefore, the examples provided in the specification that are useful for establishing discriminatory images of antigen expression

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characteristic of types of leukemia are not representative of the large genus of sets of 7 antibodies to be selected from the list provided in claim 1. Therefore, the genus of arrays of antibodies is not adequately described, and one of skill in the art would not find that applicant was in possession of the full scope of the claimed invention.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
February 4, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
2/4/05